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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,128	10/17/2003	Preeti G. Lal	PF-0549-3 DIV	1749

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,128	LAL ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-2, 17-18, drawn to an isolated polypeptide comprising SEQ ID NO:1, fragments thereof, and compositions thereof; classified in Class 530, subclasses 395.

II. Claims 3-7, 9-10, 12-13, drawn to an isolated polynucleotide sequences of SEQ ID NO:2 encoding a polypeptide of SEQ ID NO: 1; vectors, host cells, and methods of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

III. Claim 8, drawn to a transgenic organism comprising a recombinant polynucleotide of SEQ ID NO: 2, classified in Class 800, subclass 14.

IV. Claims 11, 31-32, 34 and 36-43, drawn to an antibody against SEQ ID NO:1 and compositions thereof; classified in Class 530, subclass 387.3, and 391.1; Class 424, subclass 133.1.

V. Claims 14-16, drawn to a method of detecting a target polynucleotide, classified in Class 435, subclass 6.

VI. Claim 19, drawn to a method for treating a disease or condition associated with decreased expression of functional GOLY, comprising administering to a patient composition comprising SEQ ID NO:1, classified in Class 514, subclass 12.

VII. Claims 20 and 27, drawn to a method of screening a compound for effectiveness as an agonist of a polypeptide of SEQ ID NO: 1; classified in Class 435, subclass 7.1.

VIII. Claim 21, drawn to a composition comprising an agonist compound identified by a screening method; classified in Class 514, subclass 12.

IX. Claim 22, drawn to a method for treating a disease or condition associated with decreased expression of functional GOLY comprising administering to a patient a composition comprising an agonist compound identified by a screening method; classified in Class 424, subclass 184.1.

X. Claim 23 and 27, drawn to a method of screening a compound for effectiveness as an antagonist of a polypeptide of SEQ ID NO: 1; classified in Class 435, subclass 7.1.

XI. Claim 24, drawn to a composition comprising an antagonist compound identified by a screening method; classified in Class 514, subclass 12.

XII. Claim 25, drawn to a method for treating a disease or condition associated with decreased expression of functional GOLY comprising administering to a patient a composition comprising an antagonist compound identified by a screening method; classified in Class 424, subclass 184.1.

XIII. Claim 26, drawn to a method of screening for a compound that specifically binds to the polypeptide of SEQ ID NO:1, classified in Class 435, subclass 7.1.

XIV. Claim 28, drawn to a method of screening for a compound for effectiveness in altering expression of a target polynucleotide of SEQ ID NO:2, classified in Class 435, subclass 6.

XV. Claim 29, drawn to a method of screening for potential toxicity of a test compound using hybridizing probe of SEQ ID NO:2, classified in Class 435, subclass 6.

XVI. Claim 30, drawn to a method for a diagnostic test for a condition or disease associated with expression of GOLY in *a biological sample* with an antibody against SEQ ID NO:1, classified in Class 435, subclass 7.1.

XVII. Claims 33 and 35, drawn to a method of diagnosing a condition or disease associated with the expression of GOLY in *a subject* using a composition comprising an antibody to SEQ ID NO: 1, classified in Class 424, subclass 9.1.

XVIII. Claim 44, drawn to a method of detecting a polypeptide comprising an amino acid sequence of SEQ ID NO: 1 with an antibody against SEQ ID NO: 1; classified in Class 435, subclasses 7.1.

XIX. Claim 45, drawn to a method of purifying a polypeptide with an antibody against SEQ ID NO: 1; classified in Class 530, subclass 413.

XX. Claims 46 and 48-55, drawn to a microarray comprising SEQ ID NO:2, classified in Class 436, subclass 504.

XXI. Claim 47, drawn to a method of generating an expression profile of a sample which contains polynucleotides comprising labeling the polynucleotides of the sample and contacting the elements of the microarray which comprises SEQ ID NO:2 with the labeled polynucleotides, classified in Class 436, subclass 504.

2. Groups I-IV, VIII, XI and XX are different products. Nucleic acids, polypeptides, and antibodies to the polypeptides, agonist, antagonist and arrays differ with respect to

their structures and physicochemical properties; therefore each product is patentably distinct.

3. Groups V-VII, IX-X, XII-XIX and XXI are different methods. A method of screening, a method of treating, a method of purifying, a method of detecting and a diagnostic test differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. Groups (V, XIV-XV)/II, (VI-VII, X, XIII)/I, (XVI-XIX)/III, IX/VIII, XII/XI and II-V are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used for making an anti-idiotypic antibody, in addition to the methods of treating and detecting recited. The polypeptide of Group I, can be prepared by processes which are materially different from recombinant DNA expression such as chemical synthesis or by isolation and purification from natural sources, and the polynucleotide of Group II can be use in gene therapy. The Array of Group XX can be use to identify particular DNA sequence in addition to the recited methods.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the

rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 19, 2004

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